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Counterclaim Plaintiffs
Dr. Reddy's Laboratories, Ltd. and
Dr. Reddy's Laboratories, Inc.

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE and ASTRAZENECA LP, KBI INC. and KBI-E, INC.,	07-CV-6790 (CM)(GWG)
Plaintiffs and Counterclaim Defendants,	
v.	
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.	
Defendants and Counterclaim Plaintiffs.	

THIRD DECLARATION OF HARRY G. BRITTAIN, PhD, FRSC
(FILED IN SUPPORT OF DRL'S MOTION FOR SUMMARY JUDGMENT)

1. I am the same Harry G. Brittain, PhD, FRSC, who filed a declaration in support of DRL's Motion for Summary Judgment on July 8, 2008. A summary of my credentials and professional experience was provided in that declaration, as well as a copy of my curriculum vitae.

2. I have received the Chemistry Manufacturing and Controls Section of Abbreviated New Drug Application # 78-878 and associated Supplements and Amendments [DRL 00001 to DRL 02971; DRL 03855 to DRL 03871], and portions of Drug Master File # 17707 and associated Supplements and Amendments [DRL 02972 to DRL 03854] filed by Dr. Reddy's Laboratories for Omeprazole Magnesium Delayed-Release Capsules, 20 mg. In developing the opinions expressed in this Declaration, I have reviewed and relied upon the sections of these documents that were relevant to my opinions [DRL 03674 to DRL 03854, and DRL00543 to DRL 001421].

3. I have read the Declaration of Dr. Shen Luk. Nothing in Dr. Luk's Declaration supports the idea that DRL's process or product infringes any of the claims in suit.

A. Opinions Related to the Process used by Dr. Reddy's Laboratories to Manufacture Bulk Drug Substance

4. In my previous declaration of July 8, 2008, I relied upon the DRL Defendants' Answers to the AstraZeneca Plaintiffs' First Set of Interrogatories (Nos. 1-10), dated November 1, 2007, in reaching my opinions. I have now reviewed the portions of the Abbreviated New Drug Application and the Drug Master File pertaining to the manufacture of bulk drug substance. My opinions regarding the DRL bulk drug substance and its manufacture remain exactly the same as those expressed in my November 1, 2007 declaration.

5. In my previous declaration of July 8, 2008, I stated that the methanol used in the DRL process must have a water content that is less than 0.2% w/v. My reading of the DMF confirms this fact, as the water specification limit is found in one of the Process Flow Charts [DRL 03679] and in the Process Description narrative [DRL 03690].

6. I have read the Declaration of Dr. Shen Luk. Nothing in Dr. Luk's Declaration supports the idea that DRL infringes any of the process claims in suit that concern the manufacture of the bulk drug substance (i.e., claims 11 and 20 of U.S. patent 5,900,424).

7. In his Declaration, Dr. Luk opines that DRL's omeprazole magnesium is likely crystalline, and very possibly, highly crystalline. [Luk Declaration, paragraph 6] However, nowhere in his Declaration does Dr. Luk discuss how the DRL process uses water to recover omeprazole magnesium from solution. Dr. Luk discusses at length what he perceives to be deficiencies in the way DRL obtains its X-ray powder diffraction measurements, but these arguments are not relevant to the question of using water to recover omeprazole magnesium from solution.

B. Opinions Related to the Process used by Dr. Reddy's Laboratories to Manufacture Finished Drug Product

8. In my previous declaration of July 8, 2008, I relied upon the DRL Defendants' Answers to the AstraZeneca Plaintiffs' First Set of Interrogatories (Nos. 1-10), dated November 1, 2007, in reaching my opinions. I have now reviewed the portions of the Abbreviated New Drug Application and the Drug Master File pertaining to the manufacture of the finished drug product. My opinions regarding the DRL finished drug product and its manufacture remain exactly the same as those expressed in my November 1, 2007 declaration.

9. I have read the Declaration of Dr. Shen Luk. Nothing in Dr. Luk's Declaration supports the idea that DRL infringes any of the process claims in suit that concern the manufacture of the finished drug product (i.e., claim 10 of U.S. patent 5,690,960).

10. Nowhere in his Declaration does Dr. Luk opine why it would be expected that the DRL process for manufacturing its finished drug product would entail the formation of a core

material containing omeprazole magnesium that is at least 70% crystalline by means of X-ray powder diffraction.

C. Opinions Related to the Dr. Reddy's Laboratories Finished Drug Product

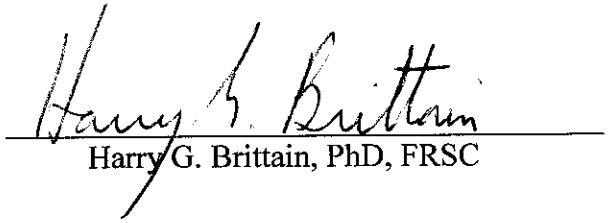
11. I have read the Declaration of Dr. Shen Luk. Nothing in Dr. Luk's Declaration supports the idea that DRL infringes any of the claims in suit that concern the finished drug product (i.e., claim 1 of U.S. patent 5,900,424 and claims 1 and 22 of U.S. patent 5,690,960).

12. Dr. Luk has opined that it makes sense that "DRL's product" contains highly crystalline omeprazole magnesium because amorphous drug substance would be less attractive to use in full scale production. [Luk Declaration, paragraph 5] However, Dr. Luk does not define what he means by "DRL's product", nor does he indicate how the use of amorphous drug substance would present problems in DRL's manufacture of its finished drug product. DRL would not be expected to encounter problems in its manufacture of finished drug product. Specifically, during the manufacture of its finished drug product DRL dissolves the omeprazole magnesium drug substance in the drug loading dispersion, which is then spray-dried onto the sealed sugar sphere cores. [DRL 00546 and DRL 00550] Any problem with handling the drug substance as an amorphous solid would be alleviated by processing the substance in a dissolved form, since any undesirable solid-state property of the amorphous substance would not exist when that substance is used in a fluidized form.

13. Nowhere in his Declaration does Dr. Luk opine why it would be expected that DRL forms a core material containing omeprazole magnesium that is at least 70% crystalline by means of X-ray powder diffraction. While Dr. Luk disparages the measurements made by DRL on its finished drug product, he does not offer any evidence that DRL's finished drug product contains omeprazole magnesium that is at least 70% crystalline.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge, information and belief.

Signed,



Harry G. Brittain, PhD, FRSC

Date: August 12, 2008

CERTIFICATE OF SERVICE

I certify that on this 13th day of August 2008, I caused a true and correct copy of the foregoing:

THIRD DECLARATION OF HARRY G. BRITTAIN, PhD, FRSC (FILED IN SUPPORT OF DRL'S MOTION FOR SUMMARY JUDGMENT)

to be served upon counsel for AstraZeneca in the following manner:

By Federal Express

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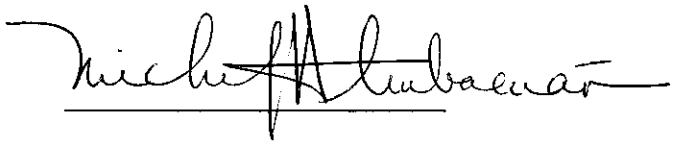

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